APR 0 3 2014

K132105

510(k) Summary

Date: April 03, 2014

Submitter: CryoLife, Inc.
Address: 1655 Roberts Boulevard NW
Kennesaw, GA 30144

Phone: 770-419-3355
Fax: 770-590-3783

Contact: Kimberly DiCono

Device Trade Name: PerClot® Topical
Common Name: Topical hemostatic particles
510(k) Number: K132105

Proposed Classification Name: Dressing, Pre-Amendment Unclassified
Product Code: FRO – General and Plastic Surgery

Predicate Device Information:

Device Name	Company	510(k) Clearance	Product Code
NexStat® Topical Hemostat Powder	Hemostasis, LLC 5000 Township Parkway St. Paul, MN 55110	K102459	FRO

Device Description:

PerClot® Topical is a medical device composed of absorbable polysaccharide granules and delivery applicators. The granules are biocompatible, non-pyrogenic and derived from purified potato starch. The granules do not contain any human or animal components. PerClot granules have a molecular structure that rapidly absorbs water, forming a gelled adhesive matrix that provides a mechanical barrier to further bleeding and results in the concentration of platelets, red blood cells, and coagulation proteins (thrombin, fibrinogen, etc.) at the site of application. The gelled adhesive matrix thus promotes the normal physiological clotting cascade. PerClot granules are enzymatically degraded by alpha-amylase and glucoamylase and by macrophages.

Intended Use:
PerClot Topical is intended for use under the care of a health care professional as a topical dressing for the temporary treatment of mildly bleeding wounds such as surgical wounds (post-operative, donor sites, dermatological), cuts and lacerations and for the treatment of mild bleeding from topical ENT surgical wounds and nosebleeds. It is also indicated for control of bleeding from the skin at percutaneous needle access, vascular access, and percutaneous catheter access sites.

Bench Testing:
Functional testing demonstrated that PerClot is substantially equivalent when compared to the predicate device.

Performance Testing:
Studies demonstrated that PerClot meets the total water absorption, rate of water absorption, adhesion/cohesion, and particle/granule size distribution specifications. The function of the product is directly related to these performance specifications. A Pre-clinical GLP evaluation was conducted according to applicable standards. This study supports PerClot's is safety and effectiveness.

Substantial Equivalence to Predicate Device:
PerClot Topical is substantially equivalent to the predicate device.

Clinical Testing:
Evaluation in a clinical setting has not been performed.

Conclusion:
Based on the functional test results, pre-clinical, and biocompatibility studies performed in accordance with ISO 10993, these products behave similarly and are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2014

CryoLife Incorporated
Ms. Kimberly DiCono
Regulatory Affairs Manager
1655 Roberts Boulevard Northwest
Kennesaw, Georgia 30144

Re: K132105
Trade/Device Name: PerClot Topical
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 26, 2014
Received: February 27, 2014

Dear Ms. DiCono:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132105

Device Name: PerClot Topical

Indications for Use:

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Prescription Use __X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S